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Rationale
- Epinephrine auto-injectors (EAI) are EpiPen and Symjepi.
- EpiPen was associated with the highest likelihood of a shorter Tmax, indicating epinephrine 0.3 mg IM was associated with the highest geometric mean Cmax in EpiPen for this Tmax category.
- The relationship between Cmax and Tmax suggests that the highest Cmax values occur when absorption is the most rapid.
- The relationship between Cmax and Tmax may contribute to unanticipated variations in PK profiles across products.

Methods
- An integrated PK analysis was conducted on randomized crossover clinical trials designed to compare the PK profiles of epinephrine 0.3 mg IM in EpiPen and Symjepi.
- The Cmax distribution for subjects who had a Tmax ≥45 minutes suggests that the software in the highest geometric mean Cmax of EpiPen for the 45 >45 minutes category is likely driven by the proportion of subjects with a Cmax of >1000 pg/mL.
- The analysis was based on the assumption that the geometric mean Cmax values associated with epinephrine 0.3 mg IM are comparable for the treatment of anaphylaxis.
- These data represent the most in-depth comparison of the PK profiles of these products.
- The results of the current epinephrine injection products approved by the US Food and Drug Administration demonstrate that there are notable differences in the PK profiles of these products.

Results
- The proportion of subjects reaching a Tmax ≥45 minutes was substantially higher in those who received EpiPen compared to Symjepi.
- The relationship between Cmax and Tmax is observed for all 3 injection products and may contribute to unanticipated variations in PK profiles across products.

Conclusions
- The EpiPen was associated with the highest likelihood of a shorter Tmax, indicating that epinephrine 0.3 mg IM is associated with the highest likelihood of a shorter Tmax following both Symjepi and EpiPen injection products.
- Risk of intra-blood vessel injection with EpiPen may contribute to unanticipated variations in PK profiles across products.

References